

Exhibit 12

Kast, Galen

From: Runkle, Patrick <Patrick.R.Runkle@usdoj.gov>
Sent: Wednesday, May 24, 2017 2:41 PM
To: Linehan, Patrick
Cc: Sullivan, David; Martin, Errin (USATXN); Mike Uhl (muhl@fhsulaw.com); mgibson@bp-g.com; Richard.Roper@tklaw.com; cass.weiland@squirepb.com; Niewoehner, Christopher; BenOmran, Arwa; Sohn, Francis; Cookingham, Andrew (Andrew.Cookingham@tklaw.com)
Subject: RE: Expert items
Attachments: 20160318 letter from Runkle to Fragale.pdf

Patrick –

On the first question, CDC is not part of the prosecution team. I've attached the letter I sent in March 2016 discussing that.

On the second question, Dr. Klontz obtained and reviewed the patient records that we provided to you, but I'm not sure exactly what "relied on" means in this context (and the civil rules revolve around the verb "considered") so I can't commit to that. Also Rule 16 speaks about providing the "bases and reasons" for the expert's opinions, and I believe we have provided those.

Best,
Patrick

From: Linehan, Patrick [mailto:PLinehan@steptoe.com]
Sent: Tuesday, May 23, 2017 2:18 PM
To: Runkle, Patrick <prunkle@CIV.USDOJ.GOV>
Cc: Sullivan, David <dasulliv@CIV.USDOJ.GOV>; Martin, Errin (USATXN) <Errin.Martin@usdoj.gov>; Mike Uhl (muhl@fhsulaw.com) <muhl@fhsulaw.com>; mgibson@bp-g.com; Richard.Roper@tklaw.com; cass.weiland@squirepb.com; Niewoehner, Christopher <cniewoehner@steptoe.com>; BenOmran, Arwa <abenomran@Steptoe.com>; Sohn, Francis <fsohn@steptoe.com>; Cookingham, Andrew (Andrew.Cookingham@tklaw.com) <Andrew.Cookingham@tklaw.com>
Subject: RE: Expert items

Patrick,

Thanks for your response. I understand the Government's position as set forth below, with two areas I hope you can clarify.

First, is it the Government's position that files within the CDC's possession, custody or control are not within the scope of the Government's discovery obligations under Rule 16(a)(1)(E)?

Second, as to Dr. Klontz, you state that the "MEDICAL RECORDS" directory in the May 1 production are "the records that were **obtained** by Dr. Klontz and the FDA's outbreak response team." Please confirm that these records constitute all of the records for these patients on which Dr. Klontz **relied** in forming his opinions as set forth in the Government's Notice of Testimony. See Government's Notice of Testimony, at 55 (Dr. Klontz will discuss his professional opinion that, based on epidemiological evidence collected from **a review of patient medical records...**) (emphasis added). Also, Please

confirm that these records constitute all of the patient records referred to and/or relied upon in Dr. Klontz's 2015 article, which was incorporated by reference into his notice of testimony.

Best,

Patrick

From: Runkle, Patrick [<mailto:Patrick.R.Runkle@usdoj.gov>]

Sent: Friday, May 19, 2017 2:14 PM

To: Linehan, Patrick

Cc: Sullivan, David; Martin, Errin (USATXN); Mike Uhl (muhl@fhsulaw.com); mgibson@bp-g.com; Richard.Roper@tklaw.com; cass.weiland@squirepb.com; Niewoehner, Christopher; BenOmran, Arwa

Subject: RE: Expert items

Patrick –

Thanks for your email. On the media you received on May 1, there's a directory called "MEDICAL RECORDS." Those are the records that were provided to Dr. Bonkovsky, and those are also the records that were obtained by Dr. Klontz and the FDA's outbreak response team (CORE) during the outbreak and, hence, were considered by Dr. Klontz as well. (We verified that many of these records were also provided in earlier Government discovery productions.) Our understanding from Dr. Klontz is that these medical records were not simple to obtain, and that the process involved HIPAA waivers for some of the patients. As far as we know (and we have made requests to the relevant portions of FDA that we believe could have records), these are the records of the liver injuries that FDA obtained. The records were provided to you in the form, as we understand, that FDA received them—meaning that if they are redacted, FDA received the records in a redacted form. To the extent that the other entities you mention have other records, we do not believe we have "possession, custody, or control" of them. *United States v. Trevino*, 556 F.2d 1265, 1271 (5th Cir. 1977).

As we noted during our meet-and-confer several weeks ago, we are declining your requests to identify specific patients in the context of your inquiries, which we believe are an attempt to force us to disclose trial evidence and trial witnesses long before we are required to do so. The discovery we have provided (including the earlier productions as well as the expert disclosures and production) gives you information about many people who appear to have been injured by USP Labs products. Additionally, your client has been sued by well over 100 persons who allege that they were injured by USP Labs products.

Best,

Patrick

From: Linehan, Patrick [<mailto:PLinehan@steptoe.com>]

Sent: Friday, May 19, 2017 8:04 AM

To: Runkle, Patrick <prunkle@CIV.USDOJ.GOV>

Cc: Sullivan, David <dasulliv@CIV.USDOJ.GOV>; Martin, Errin (USATXN) <Errin.Martin@usdoj.gov>; Mike Uhl (muhl@fhsulaw.com) <muhl@fhsulaw.com>; mgibson@bp-g.com; Richard.Roper@tklaw.com; cass.weiland@squirepb.com; Niewoehner, Christopher <cniewoehner@steptoe.com>; BenOmran, Arwa <abenomran@Steptoe.com>

Subject: RE: Expert items

Patrick,

My apologies for the delayed response – I’ve been out of town dealing with a death in the family. Regarding your first question, we’ve confirmed that the thumb drive contains all materials Defendants intended to send – i.e., the materials identified in the second and third bullet points. The material in the first bullet is publicly available at the websites set forth therein.

Regarding your second question, these materials consist of documents produced by a third party, Queen’s Medical Center, in connection with civil litigation pending in federal court in Hawaii to which USPlabs is a party. My understanding is that this material is subject to a protective order. We are currently addressing this issue with QMC’s counsel. However, given FDA’s and CDC’s close communications with QMC during the course of the investigation into the Hawaii cases, you may be able to more quickly persuade QMC to permit Defendants’ production of those documents to you.

Relatedly, Defendants have some concerns regarding the Government’s disclosures and most recent expert-related production. I will follow up with a more detailed correspondence regarding the Government’s other proposed experts, but the most pressing issue relates to Dr. Bonkovsky and his reliance upon patient files and certain research articles that in turn rely on certain patient files.

First, the disclosure for Dr. Bonkovsky asserts that his conclusion regarding the purported outbreak of serious liver injury in 2013 is based on, *inter alia*, “patient medical records,” and that the records of those “several” patients “have been provided to the defense.” Government Notice of Testimony, at 5, 13. This leaves unclear which of the 53 patients whose records Defendants have received were relied upon by Dr. Bonkovsky in forming this conclusion. Please let us know upon which of these patients’ files Dr. Bonkovsky bases his conclusions.

Second, regarding the Government’s most recent production of medical records, it is now clear to us that there may be additional files relating to these patients that either (1) the Government has yet to produce, or (2) have been produced by plaintiffs in the various civil lawsuits. Please (1) confirm that all patient medical records that have been reviewed by Dr. Bonkovsky in forming his conclusions are included in this most recent production, and (2) if any medical records for these patients have not yet been produced, produce immediately any such records in the Government’s possession, custody or control. Under the assumption that the Government has already produced all such records, Defendants are now seeking, to the extent necessary, consent from counsel to permit USPlabs’ civil litigation team to share these records with the criminal defense team for use in this case. Given that you have a line of communication with the law firm representing most of these plaintiffs (Andrews Thornton), we would appreciate you conveying to Andrews Thornton the importance of full disclosure of these records in this case.

Third, as set out in his disclosure, Dr. Bonkovsky’s conclusions are also based on the following “peer-reviewed research,” all of which is based on analysis of patients purportedly injured by OEP NF: (1) Roytman et al., *Am J. Gastroent.* 2014; 109: 1296-1298; (2) Johnston DI et al., *Drug Testing Analysis* 2016; 8:319-327; (3) Abstract of Poster #21: Severe Acute hepatocellular injury attributed to OxyElite Pro: observations from the DILIN Network; NIH-AASLD Workshop, NIH, Bethesda, MD, May 4-5, 2015, with peer-reviewed full paper appearing in *Digestive Diseases and Sciences* 2016; 61(9): 2741-48, erratum at *DDS* 2016; 61(12): 3638; (4) *MMWR*, Oct. 11, 2013/62 (40); 817-819; and (5) Centers for Disease Control and Prevention, “Acute hepatitis and liver failure of unknown etiology in Hawaii – 2013: Report of a Cluster Investigation.” In order for Defendants to assess the reliability of these research articles, identification of the patients that underlie each of these studies is necessary. Accordingly, please (1) identify each of the patients discussed in each of these articles, and (2) produce immediately all medical files for such patients in the Government’s possession, custody or control (to the extent not already produced).

Finally, the Government’s recent production of medical records includes those of patients whose identities are redacted. Please identify those patients so that Defendants can pursue additional third-party discovery and inquiries relating to those patients’ medical histories.

Given the current motions schedule, your prompt attention to these issues would be greatly appreciated.

Patrick

From: Runkle, Patrick [<mailto:Patrick.R.Runkle@usdoj.gov>]
Sent: Tuesday, May 16, 2017 10:27 AM
To: Linehan, Patrick; Niewoehner, Christopher
Cc: Sullivan, David; Martin, Errin (USATXN); Mike Uhl (muhl@fhsulaw.com); mgibson@bp-g.com; Richard.Roper@tklaw.com; cass.weiland@squirepb.com
Subject: Expert items

Patrick –

Thank you for your letter (attached) that I received today. When we opened the thumb drive, we found five Excel spreadsheets that appear to collect information related to Dr. Gibbons' testimony. I'm assuming this material is the third bullet point under your first list paragraph. We did not locate material on the thumb drive from the other bullet points. Please confirm that the thumb drive we received had all the files on it that you intended to send.

Also, although we are generally aware of the Straub docket, the Pennsylvania state court records in that case are behind a paywall. It would be helpful for you to direct us to the material in your second list paragraph from the Straub case, if it is filed publicly. If it is not filed publicly, we do not believe we have it, and we request that you send it to us.

Best,
Patrick